

Office Action Summary	Application No.	Applicant(s)	
	09/902,651	NAKANE ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 June 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,4,6,7,11-16,49-53 and 64 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,4,6,7,11-16,49-53 and 64 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 12 July 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 08/898,560.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20080812</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of the Application

- [1] Claims 1, 3-4, 6-7, 11-16, 49-53, and 64 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 6/3/08, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Applicant's arguments filed on 6/3/08 in response to the Office action mailed on 1/7/08 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [4] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Informalities

- [5] This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest in order to support the consent to a reissue application required by 37 CFR 1.172(a). The assignee's ownership interest is established by:
 - (a) filing in the reissue application evidence of a chain of title from the original owner to the assignee, or

(b) specifying in the record of the reissue application where such evidence is recorded in the Office (e.g., reel and frame number, etc.).

The submission with respect to (a) and (b) to establish ownership must be signed by a party authorized to act on behalf of the assignee. See MPEP § 1410.01.

An appropriate paper satisfying the requirements of 37 CFR 3.73 must be submitted in reply to this Office action.

[6] The objection to the reissue oath/declaration filed with this application as being defective (see 37 CFR 1.175 and MPEP § 1414) is maintained because of the following: 1) the reissue Declaration states, "duty to disclose under 37 CFR 1.56(a)." However, the duty to disclose should be made under all sections of 37 CFR 1.56, not just 37 CFR 1.56(a) and 2) claims 19-34, which are newly added to address the error which is relied upon in the Reissue Declaration filed on 7/12/01 to support the reissue application (see particularly items 7 and 8 at pp. 3-4 of the Reissue Declaration), are now canceled and can no longer provide a basis for the Reissue application. Appropriate correction is required.

RESPONSE TO ARGUMENT: At the bottom of p. 9 of the instant remarks, applicant acknowledges the instant objection to the reissue oath/declaration and responds by stating that "The defective reissue oath/declaration will be corrected by submitting a substitute reissue oath/declaration when...the Examiner indicates that the reissue application is in a condition for allowance".

As the defective reissue declaration has not been corrected, the objections to the reissue Declaration as set forth in the prior Office action and reiterated above are maintained for the reasons of record.

[7] Applicant is reminded of MPEP 1444.II, which states (in relevant part), “[a] supplemental oath/declaration need not be submitted with each amendment and additional correction. Rather, it is suggested that the reissue applicant wait until the case is in condition for allowance, and then submit a cumulative supplemental reissue oath/declaration pursuant to 37 CFR 1.175(b)(1).

Claim Objection

[8] The objection to claims 11 and 16 in the recitation of “an enzyme” is withdrawn in view of the claim amendment to replace “an enzyme” with “the mutant prenyl diphosphate synthase”.

[9] The objection to claim 15 as reciting “coding for” is withdrawn in view of the claim amendment to replace “coding for” with “encoding”.

[10] The objection to claims 49-53 as omitting claim status identifier “(New)” is withdrawn upon further consideration of the objection.

[11] Claim 64 is objected to as being misnumbered and should be renumbered as claim 54 since the immediately prior claim is numbered 53.

Claim Rejections – Defective Oath/Declaration

[12] The rejection of claims 1, 3-4, 6-7, 11-16, 49-53, and 64 as being based on a defective Oath/Declaration is maintained for the reasons noted above.

RESPONSE TO ARGUMENT: At the top of p. 9 of the instant remarks, applicant acknowledges the defective reissue oath/declaration and responds by stating that "the defective reissue oath/declaration will be replaced with a substitute reissue oath/declaration when the Examiner indicates that the application is in a condition for allowance".

As the defective reissue declaration has not been corrected, the objections to the reissue Declaration as set forth in the prior Office action and reiterated above are maintained for the reasons of record.

Claim Rejections - 35 USC § 112, Second Paragraph

[13] The rejection of claims 15-16 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "the expression product" in claim 15 is withdrawn in view of the claim amendment to replace "expression product" with "mutant prenyl diphosphate synthase".

Claim Rejections - 35 USC § 112, First Paragraph

[14] The new matter rejection of claims 2, 7, and 16 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the claim amendment to cancel claim 2 and to recite

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conditions for determining thermostability in claim 7 and farnesyl diphosphate production in claim 16.

[15] The written description and scope of enablement rejections of claims 13-14 under 35 U.S.C. 112, first paragraph, are withdrawn in view of the claim amendment to replace “a DNA” in claim 13 with “the DNA”.

[16] The written description rejection of claim 12 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 15 beginning at p. 7 of the 1/7/08 Office action.

RESPONSE TO ARGUMENT: Beginning at p. 10, bottom of the instant remarks, applicant argues the rejection is obviated by amendment to replace the phrase “a DNA according to claim 11” with “the DNA according to claim 11”.

Applicant’s argument is not found persuasive. The examiner maintains the position that the specification fails to describe the genus of claimed RNAs. The DNA of claim 12 is not limited to encoding *only* the synthase of claim 1, but further encompasses any additional nucleotide sequence at the 5’ and/or 3'-end(s) and the genus of RNAs of claim 12 encompasses an RNA that is transcribed from that additional sequence at the 5'- and/or 3'-end(s).

The Federal Circuit in *UC California v. Eli Lilly* (43 USPQ2d 1398) has said that a sufficient written description of a genus of DNAs may be achieved by a recitation of a

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representative number of DNAs defined by nucleotide sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

In this case, the specification discloses five representative species of the claimed genus of RNAs or recombinant vectors, *i.e.*, an RNA encoding Mutant enzyme 1: SEQ ID NO:1, except Thr78 is replaced with Phe and His81 is replaced with Ala; Mutant enzyme 2: SEQ ID NO:1, except Thr78 is replaced with Phe and His81 is replaced with Leu; Mutant enzyme 3: SEQ ID NO:1, except Phe77 is replaced with Tyr, Thr78 is replaced with Phe, and His81 is replaced with Leu; Mutant enzyme 4: SEQ ID NO:1, except Phe77 is replaced with Tyr, Thr78 is replaced with Phe, and His81 is replaced with Ala; Mutant enzyme 5: SEQ ID NO:1, except Phe77 is replaced with Tyr, Thr78 is replaced with Ser, Val80 is replaced with Ile, Ile84 is replaced with Leu, and an insertion

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of Pro-Ser between Ile84 and Met85 OR a recombinant vector encoding Mutant enzyme 1, 2, 3, 4, or 5. Other than these five representative species of each respective genus, the specification fails to describe any additional representative species of the claimed genus of RNAs or recombinant vectors.

In this case, the genus encompasses all species of RNAs transcribed from or recombinant vectors comprising “DNA encoding an enzyme according to claim 1” as noted above. The specification fails to disclose any other members of the genus, which broadly, but reasonably encompasses RNA that is transcribed from that additional sequence at the 5'- and/or 3'-end(s) as noted above. It is the examiner’s position that the five disclosed representative species of each respective genus fail to reflect the variation among the members of the genus, which encompass widely variant species with respect to both structure and function.

Given the lack of description of a representative number of polypeptides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

In the interest of compact prosecution, it is noted that the instant rejection would appear to be obviated by amendment to claim 12 to re-write the claim as follows:
An RNA encoding the mutant prenyl diphosphate synthase according to claim 1.

[17] The scope of enablement written description rejection of claim 12 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set

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forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 16 beginning at p. 11 of the 1/7/08 Office action.

RESPONSE TO ARGUMENT: Beginning at p. 11, top of the instant remarks, applicant argues the rejection is obviated by amendment to replace the phrase “a DNA according to claim 11” with “the DNA according to claim 11”.

Applicant’s argument is not found persuasive. The examiner maintains the position that the specification fails to enable the full scope of claimed RNAs. As noted above, the DNA of claim 12 is not limited to encoding *only* the synthase of claim 1, but further encompasses any additional nucleotide sequence at the 5’ and/or 3'-end(s) and the genus of RNAs of claim 12 encompasses an RNA that is transcribed from that additional sequence at the 5'- and/or 3'-end(s).

Here, the enablement provided by the disclosure of the specification is not commensurate with the scope of the claim, particularly with respect to the scope of RNAs. As noted in the prior Office action, the specification fully enables an RNA encoding Mutant enzyme 1, 2, 3, 4, or 5 as set forth above. As noted in the prior Office action, the specification discloses only five working examples encompassed by the scope of the claimed RNAs, *i.e.*, an RNA encoding Mutant enzyme 1, 2, 3, 4, or 5 as set forth above. Other than RNAs encoding Mutant enzyme 1, 2, 3, 4, or 5, the specification fails to teach how to use those RNAs that are transcribed from *any* DNA encoding the mutant of claim 1, which, as noted above, is not limited to encoding *only* the synthase of claim 1, but further encompasses any additional nucleotide sequence at the 5’ and/or 3'-end(s). While methods of transcribing RNA from DNA were known at the time of the

invention, it was not routine to make and test all RNAs as encompassed by the claims, particularly as the specification fails to provide guidance for using all RNAs as encompassed by the claims that do not translate the protein of claim 1.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of experimentation that is required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In the interest of compact prosecution, it is noted that the instant rejection would appear to be obviated by amendment to claim 12 to re-write the claim as follows:
An RNA encoding the mutant prenyl diphosphate synthase according to claim 1.

Conclusion

[18] Status of the claims:

- Claims 1, 3-4, 6-7, 11-16, 49-53, and 64 are pending.
- Claims 1, 3-4, 6-7, 11-16, 49-53, and 64 are rejected.

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- No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
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